DUAL NEUTRALISATION OF INTERLEUKIN (IL)-17A AND IL-17F WITH BIMEKIZUMAB IN MODERATE-TO-SEVERE PLAQUE PSORIASIS: 60-WEEK RESULTS FROM A RANDOMISED, DOUBLE-BLINDED, PHASE 2B EXTENSION STUDY

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Background: Psoriasis is a chronic, systemic, immune-mediated inflammatory disease associated with prominent skin manifestations. One in four patients with psoriasis also has psoriatic arthritis, with skin disease preceding joint manifestations in most patients.1 Interleukin (IL)-17F shares structural homology and pro-inflammatory function with IL-17A. Preclinical and early clinical data support dual neutralisation of IL-17F, together with IL-17A, as a novel targeting approach for the treatment of immune-mediated inflammatory diseases. Bimekizumab, a monoclonal antibody that potently and selectively neutralises both IL-17A and IL-17F, is in development for the treatment of psoriasis, psoriatic arthritis and ankylosing spondylitis.3-5 In the 12-week BE ABLE 1 study (NCT02905006), bimekizumab provided rapid and substantial clinical improvements in patients with moderate-to-severe plaque psoriasis, with a safety profile consistent with previous bimekizumab studies.3,4

Objectives: The objectives of this Phase 2b extension study (BE ABLE 2; NCT03010527) were to assess the long-term safety and efficacy of subcutaneous bimekizumab every four weeks for an additional 48 weeks (60 weeks’ total exposure).

Methods: BE ABLE 1 responders (>90% reduction in Psoriasis Area Severity Index [PASI90] at Week 12) receiving placebo or bimekizumab 64mg, 160mg, 160mg (320mg loading dose [LD]) remained on the same dose; non-responders (>PASI90 at Week 12) were re-assigned from placebo/bimekizumab 64mg to 160mg or from 160mg/160mg (LD) to 320mg. Patients previously receiving bimekizumab 320mg/480mg received 320mg. The primary variable was the exposure-adjusted incidence rate (EAIR) of treatment-emergent adverse events (TEAEs); efficacy assessments were secondary.

Results: 217 patients were enrolled. Across all doses, BE ABLE 1 responders generally maintained complete or almost complete skin clearance for up to an additional 48 weeks: PASI90: 80–100%, non-responders imputation (93–100%, observed); PASI100: 70–83% (80–96%); Investigator’s Global Assessment: 78–100% (98–100%). PASI100 was achieved by 33–76% (40–82%) of non-responders (Week 48). EAIR of TEAEs was 206.1/100 patient-years (n=184/217 [85%]). EAIR of serious TEAEs was 6.2/100 patient-years (n=15/217 [7%]); no serious TEAE was reported by >1 patient. The most frequent TEAEs were oral candidiasis and nasopharyngitis. No cases of suicidal ideation/behaviour, major adverse cardiac events, or inflammatory bowel disease were reported. No new safety findings were observed.

Conclusion: Nearly all BE ABLE 1 responders completing 60 weeks of bimekizumab treatment maintained complete or almost complete skin clearance, with a safety profile consistent with previous studies.3,4

REFERENCES

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